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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,059	12/22/2005	Yasuhiro Kajihara	ACT-003	9645

20374 7590 07/14/2009

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EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	
MAIL DATE	DELIVERY MODE
07/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,059	KAJIHARA ET AL.	
	Examiner	Art Unit	
	ERIC S. OLSON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-8,12,13,15,16 and 21-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2-8,12,13,15 and 16* is/are allowed.

6)☒ Claim(s) *21-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 9, 2009 has been entered.

Detailed Action

This office action is a response to applicant's communication submitted March 9, 2009 wherein claims 2, 5, and 8 are amended and new claims 21-31 are introduced. This application is a national stage application of PCT/JP04/09521, filed June 29, 2004.

Claims 2-8, 12, 13, 15, 16, and 21-31 are pending in this application.

Claims 2-9, 12, 13, 15, 16, and 21-31 as amended are examined on the merits herein.

Applicant's amendment, submitted March 9, 2009, with respect to the rejection of instant claims 2-8, 12, 13, 15, and 16 under 35 USC 112, first paragraph, for lacking enablement for all asparagine-linked fatty acid amides, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require a certain specific oligosaccharide structure. Therefore the rejection is withdrawn.

Applicant's amendment, submitted March 9, 2009, with respect to the rejection of instant claims 2-5, 7, 8, 12, and 13 under 35 USC 102(b) for being anticipated by Michel et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the compounds not contain any amino acids other than the asparagine. Therefore the rejection is withdrawn.

Applicant's amendment, submitted March 9, 2009, with respect to the rejection of instant claims 6 and 14-16 under 35 USC 103(a) for being obvious over Michel et al. in view of Remington, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the compounds not contain any amino acids other than the asparagine. Therefore the rejection is withdrawn.

Applicant's amendment necessitates the following new grounds of rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating influenza, does not reasonably provide enablement for a method of treating any and all viral diseases. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is a method for treating viral diseases. In order to be enabled for the full scope of the invention, one skilled in the art must be able to treat all disorders falling within the scope of the claims without undue experimentation.

The state of the prior art: Influenza viruses invade cells by binding to sialic acids. The proteins hemagglutinin and neuraminidase are essential for this process and are targets of antiviral therapy. For example, the neuraminidase inhibitors ostelamivir and zanamivir are commonly used for the treatment of influenza, as disclosed in the drug label for ostelamivir and the MedlinePlus drug information for zanamivir. (both included with PTO-892) This class of therapeutic agents is used specifically for treatment of influenza, and is not known in the art to be useful for treating any viral infections other than influenza.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: Viruses are extremely varied, infecting different cell types and using different proteins for cell invasion and reproduction. Because of the extreme simplicity of the viral genome, viruses lack many of the basic metabolic and housekeeping genes of other organisms and rely on their hosts to perform most biological functions. As a consequence there is a dearth of molecular targets for antiviral therapy. Those viral-specific genes which are available as therapeutic targets, for example sialidase for influenza or reverse transcriptase for HIV, are specific to certain viral species and are not common to all viruses. Therefore the field of antiviral therapy is complex and unpredictable, with no expectation that one therapeutic approach can be successful for all viruses.

The Breadth of the claims: The claimed invention is extremely broad, encompassing methods of treating any viral infection in a subject.

The amount of direction or guidance presented: The specification discloses the claimed oligosaccharides as sialidase inhibitors and specifically discusses their use for the treatment of influenza. Although the specification also states that these compounds are useful broadly for treating viral infections, no indication is provided as to whether they target any viral proteins other than sialidase/neuraminidase or how they could affect viruses that do not express sialidase.

The presence or absence of working examples: No working examples are provided for the actual treatment of influenza or any other viral infection in a living subject.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the broad-spectrum treatment of unrelated disorders. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the claimed invention for the full scope of the claims, namely for treating all possible viral disorders, one skilled in the art would have to first develop methods for treating viral disorders other than influenza. Doing so would require that one skilled in the art apply the claimed compounds to molecular targets other than sialidase, in order to treat non-sialidase-expressing viral species. Doing so would involve extensive study of these saccharides to determine what activities they possess other than sialidase inhibition and then further experimentation to determine what viral species could be inhibited by these activities. This process would involve an undue burden of unpredictable experimentation.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims and the lack of guidance or working examples, Applicants fail to provide information sufficient to practice the claimed invention for treating all possible viral infections.

Conclusion

Claims 21-31 are rejected. Claims 2-8, 12, 13, 15, and 16 are seen to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
7/13/2009